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| 10/513,961      | 12/20/2004  | Michael R Boyd       | 231119              | 4710             |

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| EXAMINER |
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LUCAS, ZACHARIAH

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| ART UNIT | PAPER NUMBER |
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1648

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01/31/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/513,961 | <b>Applicant(s)</b><br>BOYD ET AL. |  |
|                              | <b>Examiner</b><br>Zachariah Lucas   | <b>Art Unit</b><br>1648            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-37, 39-55, 59 and 64-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-16, 18-37, 39-52, 55, 59, and 64-77 is/are rejected.
- 7) ☒ Claim(s) 2, 17, 53, and 54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/17/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1-37, 39-55, 59, and 64-77 are pending and under consideration in the application.
2. In the prior action, mailed on August 22, 2007, claims 1-55 and 57-77 were pending; with claims 1, 3-16, 18-52, 55, and 57 rejected; and claims 2, 17, 53, and 54 objected to.
3. In the Response of January 4, 2008, the Applicant amended claims 3, 18, 37, 39, 47, 52, 53, and 59; and cancelled claims 38, 57, 58, and 60-63.

#### *Information Disclosure Statement*

4. The information disclosure statement (IDS) submitted on November 21, 2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

#### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Maintained in part)** Claims 1, 3-16, 18-46, 47-52, 55, and 57-77 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 38, 57, 58, and

60-63 have been cancelled from the application. The rejection is therefore withdrawn from these claims.

The claims were rejected on three grounds.

Claims 1, 3-16, 18-37, 39-52, 55, 59, and 64-77 were rejected on the basis that there is inadequate written descriptive support for the claimed inventions to the extent that the claims read on antiviral variants and fragments of SEQ ID NO: 1, or the use thereof. The Applicant traverses this rejection by asserting that examples of such proteins have been described. In evidence, the Applicant points to page 8, paragraph [0023] of the application. The same deficiencies are found in the teachings referenced by the Applicant with respect to claims 3, 18, 37, and 47. This portion of the application provides a general description of variants of the disclosed sequence. It does not provide any specific examples of variant proteins, or identify any region or fragment of the protein that is responsible for or associated with the required function. The Applicant's argument is therefore not found persuasive, and this portion of the rejection is therefore maintained.

The second basis of the rejection was on the grounds that there is insufficient descriptive support for the genus of nucleic acids described in claim 17. This rejection was previously withdrawn.

The third basis of the rejection applied to claim 57. In view of the cancellation of this claim, this portion of the rejection is now also withdrawn.

7. **(Prior Rejection- Withdrawn)** Claims 37, 41-51, 64-73, 76, and 77 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of inhibiting HIV infection of a biological sample, does not reasonably provide enablement for methods of inhibiting HIV virus infection of a host or of inhibiting infection by other viruses than HIV. In view of the amendment of the claims, the rejection is withdrawn.

8. **(Prior Rejection- Withdrawn)** Claims 60-63 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims have been cancelled from the application. This rejection is therefore withdrawn.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **(Prior Rejection- Maintained)** Claims 52 and 55 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 6,183,961. The claim has been amended to require that the antibodies bind to one of SEQ ID NO: 1, or a protein that is 90% or more identical or homologous to that sequence. SEQ ID NO: 1 is 95 residues in length. The Flag sequence is eight residues in length. Thus, a fusion protein that comprises SEQ ID NO: 1 and a flag sequence will be at least 90% homologous or identical to SEQ ID NO: 1 ( $95/(95+8) \approx .92$ ). This portion of the rejection is therefore maintained.

11. **(Prior Rejection- Maintained)** Claims 52-55 and 57-62 are rejected under 35

U.S.C. 102(b) as being anticipated by Boyd (US 6,193,982) in light of Ziolkowska et al. (Acta Biochim Pol 53: 617-26). Claims 57, 58, and 60-62 have been cancelled from the application.

With respect to the remaining claims, the Applicant asserts that the antibodies of Boyd would not bind to scytovirin because cyanovirin and scytovirin bind to different portions of oligomannose-9. However, the antibodies of Boyd do not comprise only a portion of the oligomannose. Rather, the antibodies of the reference include an internal image of the HIV gp120, to which oligomannose-9 is bound (as is inherent to the antibodies as shown by the ability of cyanovirin to bind the antibody). Thus, the antibodies of this reference would be capable of binding both types of antiviral proteins. The rejection is therefore maintained over pending claims 52-55 and 59.

### *Double Patenting*

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1648

13. **(Prior Rejection- Maintained)** Claims 52-55 and 57-62 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,193,982 in light of Ziolkowska. For the same reasons as were indicated with respect to the anticipation rejection above, this rejection is maintained over claims 52-55 and 59.

### *Conclusion*

14. No claims are allowed. Claims 2, 17, 53, and 54 are objected to as depending from a rejected claim.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/  
Patent Examiner, AU 1648